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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,513	03/26/2001	Therese Jourdiar	MBHB00-1282	3546

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EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/720,513

Applicant(s)

JOURDIER ET AL.

Examiner

Bao Qun Li

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED _____ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 22 February 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: it still cannot overcome the obvious rejection (See detail explanation in the attachment).
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☒ Other: Interview summary.

Bao Qun Li

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Advisory Action

The response under 37 CFR 1.116 and Declaration under C.F.R. 1.132 filed on February 22, 2005 in response to the final action mailed on September 22, 2004, 2005 have been acknowledged and respectfully considered. However, they are not persuasive to overcome the obviousness rejection.

For purpose of appeal, the status of the claims is as follows:

Allowed claim(s): NONE.

Rejected claim (s): 10-15.

Claim(s) objected to: NONE.

Claim Rejections - 35 USC § 103

Claims 10-15 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Carrano et al. (WO 95/26718A1), Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403), Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut) and Bouvet et al. (Infect. Immun. 1994, Vol. 62, pp. 3957-3961) under the same ground as stated in the previous Office Action.

In response to the previous Office Action, applicants filed a Declaration under 37 CFR 1.132 asserting thigh injection can induce both systemic and local specific immune response.

The Argument and declaration have been respectfully considered. However it is not persuasive to overcome the rejection. Although the data in the declaration has shown that the thigh injection can induce both systemic and local specific IgG and IgA, the data does not contradict to the examiner's opinion that the local immune response from the thigh injection increases more significantly specific IgG and IgA immune responses in the area closest to the injection site, and include external, internal iliac lymph nodes and inguinal lymph nodes. The antigen injected in the thigh area is delivered to the lymph nodes initially via the femoris vein. For specific immunoglobulin induction in a lymph node, the closer to the femoris vein circulation, the faster and greater the immune response will likely be.

Moreover, the Declaration is insufficient to overcome the rejection, because the declaration still does not provide control data to answer the question raised in the previous Office Action, i.e. why thigh injection as a known and very common immunization site is a non-obvious selection and how the claimed method is considered as an unexpected result since no

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control group was set in the disclosed experiments of the specification. In other words, there is no control experiment to answer the following questions:

- 1). Whether other muscular injection site is able to induce a similar patter of systemic and local specific immune response as compared with thigh injection,
- 2). Whether such immune response only occurs to the claimed sexual transmitted disease, in other word, if injection of other pathogen in the thigh area does not induce such pattern of specific immune response.

Thigh injection is common place for administering an immunogenic composition known and used for years in the clinic. More importantly, Stities et al. and Groswasser et al. cited in the previous office action teach that thigh injection is preferred immunization sites. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated using a method of injecting an immunogenic composition locally near the genital area to product better immune response absence unexpected result.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

05/21/2005


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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